

# Exhibit 5

**PIC/S 2016 Annual Seminar - Inspectorates of the Future**

Hosted by MHRA, Museum of Science and Industry, Manchester, UK ([www.mosi.org.uk](http://www.mosi.org.uk))

6 – 8 July 2016.

**Wednesday 6<sup>th</sup> July 'Inspection trends and future developments'**

Time	Topic
09.00	Welcome to Seminar – Head MHRA Inspectorate (M Birse) Opening addresses – Chief Executive MHRA & PIC/S Chairman (I Hudson / P Hargreaves) Introduction to Agenda – Head MHRA Inspectorate (M Birse)
09.30	Inspections trends & GMP deficiencies – (P Gustafson) <ul style="list-style-type: none"> <li>Pre-seminar questionnaire – follow up from South Africa on trends</li> </ul> Deficiency classification – TGA (WG on harmonization on classification).
10.30	Break
11.00	Data Integrity - Issues identified and inspection techniques MHRA & TGA (D Churchward) <ul style="list-style-type: none"> <li>Note link back to anything in 09.30 slot</li> </ul>
11.45	Industry developments – Speaker from the GPMLF Global Pharmaceutical Manufacturers Leadership Forum or Strathclyde University Grant people or Government speaker on pharmaceutical business trend (HPRA) - MHRA to arrange
12.30	Lunch
13.30	Workshop 1 – Inspection trends and inspection strategies for the future (link to 0930 speakers +3-4 MHRA to support) P Gustafson + MHRA support <ul style="list-style-type: none"> <li>Review and comparison of trends globally – output: new PIC/S article</li> <li>Use GPMLF GPS document to map gaps in inspector knowledge – output: for PIA to use</li> </ul> Workshop 2 – Data Integrity (link to 0930 speakers +3-4 MHRA to support) (TGA/FDA/MHRA) - MHRA to arrange once delegates known <ul style="list-style-type: none"> <li>Workshop showing practical examples of how to inspect</li> <li>Gather additional techniques from group – output: for collation by drafting group</li> </ul>
15.00	Break
15.30	Workshop 1 – Inspection trends and inspection strategies for the future Workshop 2 – Data Integrity
17.00	Close

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**Thursday 7<sup>th</sup> July 'Inspectorates of the Future'**

Time	Topic
09.00	Scene setter for day - MHRA to arrange
09.10	Working together – TGA (H Rothenfluh) + EMA (P Krauze) or WHO <ul style="list-style-type: none"> <li>PIC/S, ICMRA etc</li> <li>Reliance frameworks – maximising resources</li> <li>Information sharing – what needed and when</li> <li>Practicalities &amp; legalities of Office/Desktop Based Inspections</li> </ul>
09.35	Risk based inspections – (J Morenas / Ian Jackson) <ul style="list-style-type: none"> <li>Review of PIC/S approach</li> <li>Drivers and intel needed</li> <li>Whistle-blowers</li> </ul> Pre-seminar questionnaire – MHRA to establish with session lead
10.30	Break
11.00	Compliance Management – FDA (S Laska/ E Morrison) <ul style="list-style-type: none"> <li>Increase patient safety and security of supply</li> <li>What is done beyond inspections to drive compliance</li> <li>Pre-seminar questionnaire - MHRA to establish with session lead</li> </ul>
11.45	Shortages and complex supply chain – Industry speaker (supply chain shortages group) – MHRA to arrange <ul style="list-style-type: none"> <li>Drivers for shortages / assessors view</li> <li>Increasing complexity / industry view</li> </ul>
12.30	Lunch
13.30	Workshop 3 – Shortages EMA (P Krauze/Brendan Cuddy) + MHRA support <ul style="list-style-type: none"> <li>Presentation on practical examples <ul style="list-style-type: none"> <li>Inspectors 'role' in reducing shortages / inspectors view</li> </ul> </li> <li>Greater understanding of work done in this area</li> <li>Develop guidance documents</li> <li>What can inspectors do – output: how PIC/S can promote work in this area</li> </ul> Workshop 4 – Compliance Management FDA ( with MHRA Support) <ul style="list-style-type: none"> <li>Workshop discussing what inspectors/agencies do now</li> <li>Develop what more could be done and what PIC/S could do</li> <li>Whistle-blowers, how handled</li> <li>Gather from group – output: proposals for PIC/S to develop</li> </ul>
15.00	Break
15.30	Workshop 3 – Shortages Workshop 4 – Compliance Management
17.00	Close

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**Friday 8<sup>th</sup> July 'A New Dawn'**

<b>Time</b>	<b>Topic</b>
09.00	Introduction
09.00	PIA – Now & Next (Boon) <ul style="list-style-type: none"> <li>• Overview of PIA progress to all delegates</li> <li>• What it will mean as an Inspector</li> </ul>
09.30	Workshop feedback (x4) – 15 mins each Chair HPRA (A Hayes) + leaders of the workshops <ul style="list-style-type: none"> <li>• Recap of key messages</li> <li>• Proposed output and next steps</li> </ul>
10.30	Break
11.00	Foreign Travel Safety Awareness (Harry TGA/ MHRA) <ul style="list-style-type: none"> <li>• Risk Assessments – proactive and dynamic</li> <li>• Security Alerts</li> <li>• Cancelling inspections</li> <li>• Working with inspectors in country</li> </ul>
11.30	PIC/S Highlights and Vision to 2020 – Chair (P Hargreaves) <ul style="list-style-type: none"> <li>• Developed by EB members</li> <li>• Highlights of WG and SC</li> </ul>
12.00	2017 Seminar address – Chinese Taipei
12.15	Closing address & presentation of the PIC/S walking stick <ul style="list-style-type: none"> <li>• MHRA (M Birse)</li> <li>• Chair PIC/S (P Hargreaves)</li> </ul>
12.30	Lunch or depart

Workshop structure

- 2 workshops with approximately 70 people (7 x round table of 10)
- Each workshop 1.5 hours long and then swap
- 4 facilitators per workshop (MHRA to provide 2 Inspectors to support running of each)
- Technology used to capture feedback for all teams for instant review – iPads etc and voting technology